DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

99 MAY 12 AM 9:45

ASSISTANT COMMISSIONER
FOR PATENTS

MAY - 5 1999

Re: Tazorac®
Docket No.: 98E-0474

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,089,509, filed by Allergan, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Tazorac®, the human drug product claimed by the patent.

The total length of the regulatory review period for Tazorac® is 2,684 days. Of this time, 1,958 days occurred during the testing phase and 726 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 8, 1990.

   The applicant claims February 16, 1990, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 8, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 19, 1995.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for Tazorac ® (NDA 20-600) was initially submitted on June 19, 1995.

3. The date the application was approved: June 13, 1997.

   FDA has verified the applicant's claim that NDA 20-600 was approved on June 13, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Robert J. Baran
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